

IN THE CLAIMS

Please amend the claims as follows:

1. (Cancelled)

2. (Cancelled)

3. (Cancelled)

4. (Currently Amended) The patch of claim [[1]] 15 suitable for use in the administration of DMF to a patient and characterized in that the proximal layer of the patch has a permeability to DMF, such that DMF which is, in use, located in the cavity between the layers will be released through the proximal layer at a rate below the rate which it is absorbed through the skin of the patient to which the patient is in use applied, thereby substantially preventing building up of DMF in direct contact with the skin of the patient.

5.. (Cancelled)

6. (Previously Presented) The patch of claim 4 in which the layers of a patch intended to be used for the administration of dimethylforamide as such, or of a pharmaceutical preparation containing dimethylforamide as a penetration enhancing agent, are of the same chemical composition and are made from vulcanizates of silicone.

7. (Previously Presented) The patch of claim 4 wherein the composition of the layer intended for use as a proximal layer in a patch for use in the administration of DMF as such, or of a pharmaceutical preparation containing DMF as a penetration enhancing agent, is produced to have permeability to dimethylformamide of not more than 9 mg DMF/cm²/hour.
8. (Currently Amended) The patch of claim [[1]] 15 in which the cavity defined between the proximal and distal layers of the patch construct is preferably in use filled with a solid filler material to serve as a carrier for the pharmaceutically active substance or composition received therein.
9. (Cancelled)
10. (Cancelled)
11. (Cancelled)
12. (Withdrawn) A method for administering a drug transdermally, comprising:
depositing the drug in a cavity formed between a distal layer and a proximal layer of a transdermal patch; wherein the distal layer is impermeable to the drug, and the proximal layer is permeable to the drug and adapted to be in contact with human skin; and

reducing irritation of the human skin due to components of the drug by preventing build up of the drug between the proximal layer and the human skin.

13. (Withdrawn) The method of claim 12, wherein the preventing the build up of the drug comprises reducing the permeability of the proximal layer to the drug to below the permeability of human skin to the drug.

14.(New) A patch device, comprising:

 a composite distal layer comprising a first distal layer and a second distal layer adhesively secured together; wherein the second distal layer is impervious to dimethylformamide (DMF) and a transverse passage is formed to extend transversely through the first and second distal layers ;

 a proximal layer adhesively secured to the composite proximal layer to form a cavity together with the proximal layer; said cavity holding a substance to be administered to a patient; a composition and thickness of the proximal layer being selected so that its permeability to an irritating component of said substance is less than the permeability of human or animal skin to such irritating component, thereby to reduce irritation of the human or animal skin; and

 a backing sheet on which the composite distal layer is mounted via the first distal layer, the backing sheet comprising a peripheral area around the composited distal layer, said backing layer comprising an access port to provide access the transverse passage of the composite distal layer for introduction of a substance into the cavity via a syringe; and an adhesive coating

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10581827

Filing Date: May 23, 2007

Title: PATCH

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protected with a cover which is removable to allow the patch device to be secured to the skin of the human or animal patient.